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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,877	10/02/2003	Peng Liang	03-052-PL	9984

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/677,877

Applicant(s)

LIANG, PENG

Examiner

Agnes B. Rooke

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 6-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/06/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This non-final office action is in response to the paper filed on 09/06/2006.

Claims 4, 5, and 15-19 are cancelled and claims 1-3 and 6-14 are amended.

Claims 1-3 and 6-14 are pending and under examination.

IDS

The IDS submitted on 09/06/2006 is acknowledged.

Objections Withdrawn

Objection to specification is withdrawn in view of the amendments.

Objection to claims is withdrawn in view of the amendments.

Rejections Withdrawn

The rejection of claim 1, under 35 U.S.C. 103(a) as being unpatentable over Gruber et al. is withdrawn because Gruber et al. teach the use of a recombinant nucleotide sequence containing a cDNA coding for one or several mammalian collagen chains or derived proteins, and do not teach a fusion protein of collagen that is fused to noncollagenous polypeptides.

The rejection of claims 1-3, under 35 U.S.C. 102(b) as being anticipated by Vuorio et al. is withdrawn because Vuorio et al. do not teach a method where collagen is fused to non-collagen polypeptide.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vuorio et al. (WO 97/17988) in view of Burgeson et al. U.S. 2003/0143564 A1.

Vuorio et al. teach in claims 1-7, on page 27, and in Brief Description of the Drawings on page 4, a fusion collagen, where using a method comprising culturing host cells transformed with recombinant DNA expression vector; and recovering the fusion protein from the cell culture; where different host cells, such as yeast or insect cells are used; see page 9, lines 3-10.

Vuorio et al. does not teach collagen proteins fused to non-collagen proteins.

Burgeson et al. U.S. 2003/0143564 A1 teach collagen XXII polypeptides linked to non-collagen polypeptide, see paragraphs [0013], [0072], [0147] where the non-collagen polypeptide refers to a polypeptide having an amino acid sequence corresponding to a protein, which is not substantially homologous to the collagen protein, i.e. a collagen that is different from a collagen peptide, for example. See also Abstract.

Art Unit: 1653

Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to design a method for generating a secreted soluble trimeric fusion protein comprising collagen as disclosed by Vuorio et al. and to modify the invention by incorporating a non-collagen protein in a construct, as taught by Burgeson et al. One would be motivated to design such a method because there are different methods in the prior art that utilize collagen proteins being fused to non-collagen proteins.

Examiner's Response to obviousness concern discussed during the on-phone interview on August 29, 2006.

As noted in the Applicant's Remarks section, during the telephonic interview, examiner indicated an obviousness concern of the current invention over Mohler et al., which is disclosed on page 3 of the subject matter application. The Applicant acknowledges that during the on-phone interview, examiner stated that from the disclosure of Mohler et al. and the existence of commercially available dimeric proteins, it would be obvious for one skilled in the art to produce a trimeric protein, since one skilled in the art would be motivated to produce a trimeric soluble receptor over a dimeric soluble receptor, and would further be motivated to produce tetrameric soluble receptor. See Remarks, page 26.

Applicant acknowledges that on page 1549 of Mohler et al. it is stated that "Given predominantly trimeric nature of TNF and the apparently requirement for cross-linking of

Art Unit: 1653

cell-surface TNFR for signal transduction, it is likely that dimeric soluble receptor constructs should possess a higher affinity for TNF and therefore function as a considerably more potent competitive inhibitors than monomeric sTNFR." See Remarks on page 27. Further, Applicant maintains that the instant invention is not obvious because, for example, 13 years after the creation of dimeric sTNFR, no one has come up with a way for creating secreted soluble TNFR in trimeric form. See Remarks, page 28.

Further, Applicant states that examiner based the obviousness concern during the on-phone interview in regards to Mohler et al. by pointing out that Mohler suggests that the more multivalent a soluble receptor is, the more potent it can be in binding to its ligand. See remarks, page 29. The Applicant disagrees with that assertion and states that a trimeric sTNF should have the highest binding affinity to its trimeric ligand, TNF, and thus it is not obvious to those skilled in the art that generating soluble receptors with more binding sites produces stronger binding affinities. See Remark, page 29. Further, Applicant refers examiner to Figures 4A and 4B, where the trimeric TNFR binding affinity to TNF in the standard TNF bioassay was 10-100 times more potent in TNF binding than that of the published binding affinity of dimeric sTNFR.

Examiner points out that the Drawings as currently amended, as submitted on 04/05/2004, only present Figure 4 and Figure 5 (and not Figures 4A and 4B), where Figure 5 shows the binding affinity. Also, Figure 4 cannot be interpreted since the image is not clear.

Examiner concludes that the reference of Mohler et al., J. of Immunology, vol. 151, No. 3, 1993, p. 1548-1561, is cited as a relevant prior art of record.

**Objection to the Drawings and the specification section referring to
drawings**

The specification in regards to drawings was amended several times, however there are still inconsistencies in numbering in the text of the specification versus Drawings themselves. For example, the latest amendment to the Drawings (04/05/2006) presents Figure 4 and Figure 5 (and not Figures 4A and 4B), while the amended specification in regards to drawings still refers to Figures 4A, for example. Thus, Applicant must correctly amend specification to correspond to the presented drawings. In addition, Figure 4, cannot be interpreted properly since it is scanned too dark.

Objections to claims

Claims 6-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

Art Unit: 1653

supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER